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|-------------------------------|------------------------|---------------------|--|
| <b>Notice of Allowability</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                               | 10/580,777             | BERNARD ET AL.      |  |
|                               | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                               | AARON J. KOSAR         | 1657                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the communication filed on 6/10/2011.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 1-28.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application  |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>20110826</u> . |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date <u>6/10/2011</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment  |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                    | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance                         |
|   | 9. <input type="checkbox"/> Other ____.  |

/AARON J KOSAR/  
Examiner, Art Unit 1657

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### **DETAILED ACTION**

Applicant's amendment and argument filed June 10, 2011, in response to the non-final rejection, are acknowledged and have been fully considered.

### **EXAMINER'S COMMENT**

Claims 1-28 have been examined on the merits and found allowable (as amended within the Examiner's Amendment below).

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with F.C. Eisenschenk on September 6, 2011.

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**In the Specification:**

Page 17 has been deleted.

On page 1, at line 27, the phrase “Buck and Loh 1985; Bohak et al. 1987; Petti et al. 1994; Ikonomou et al. 2002” has been omitted and replaced with the phrase:

--Buck and Loh, *J. Viriological Meth.*, 1985; Bohak *et al*, *Biopolymers*, 1987; Petti *et al*, *Biotechnol. Prog.*, 1994; Ikonomou *et al*, *Biotechnol. Prog*, 2002)--

On page 2, at line 4, after the term “disks” insert the phrase --(New Brunswick Scientific)--.

On page 2, at lines 5-7, the phrase “and See Worldwide Websites: nsbc.com/products/miscellaneous/fibracel/ and nbsc.com/support/faqs/#fibra” has been deleted.

On page 6 (at line 34); page 7 (at lines 1,2, 19-21, and 26-29); page 12 (at line 20); page 14 (at lines 22, 27, and 30); and page 16 (at lines 1, 4, and 6), at each instance of the term “ $l \cdot h^{-1} \cdot kg^{-1}$ ” has been omitted and each replaced with the term -- $l \cdot h^{-1} kg^{-1}$ --.

On page 6, at line 11, the term “(1992)” has been omitted and replaced with the phrase --(*Cytotechnology*, 1992)--.

On page 9, at line 15, the phrase “Sabu et al. 2002” has been omitted and replaced with the phrase --Sabu *et al*, *Appl.Biochem.Biotechnol.*,2002--.

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On page 11, at line 17, the recited mathematical formula has been omitted and replaced with:

$$--Ra = \frac{1}{l} \int_0^l |z(x)| dx--.$$

On page 12, at lines 18, 24 , and 26, each instance of the term “L.day<sup>-1</sup>.kg<sup>-1</sup>” has been omitted and each replaced with the term --l•day<sup>-1</sup>kg<sup>-1</sup>--.

On page 12, at line 19, the term “l.hr<sup>-1</sup>” has been omitted and each replaced with the term --l•hr<sup>-1</sup>--.

On page 12, at line 23, the term “g.day<sup>-1</sup>.kg<sup>-1</sup>” has been omitted and each replaced with the term --g•day<sup>-1</sup>kg<sup>-1</sup>--.

On page 13 (at line 14); page 15 (at lines 1 and 8); and page 16 (at lines 13 and 20), in each instance the term “EU.ml<sup>-1</sup>” has been omitted and each replaced with the term --EU•ml<sup>-1</sup>--.

On page 13 (at line 28); and page 15 (at lines 1 and 9), in each instance of the term “CFU.ml<sup>-1</sup>” has been omitted and each replaced with the term --CFU•ml<sup>-1</sup>--.

On page 16 (at line 13 and 21); and page 15 (at lines 1 and 9), in each instance of the term “CFU.100ml<sup>-1</sup>” has been omitted and each replaced with the term --CFU•100ml<sup>-1</sup>--.

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**In the Claims:**

Claims 29-32 are canceled.

Claim 1 has been amended to read as follows:

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1. A method of recycling a solid support for anchorage-dependent cell cultivation within a system for cultivation of anchorage-dependent cells, the method comprising the steps of:

- a) providing an anchorage-dependent cell cultivation system, wherein the cell cultivation system comprises a solid support and a liquid;
- b) emptying the liquid from the anchorage-dependent cell cultivation system or removing said solid support from said cell cultivation system;
- c) after step (b), rinsing the solid support with an aqueous solution;
- d) after step (c), rinsing the solid support with a sodium hydroxide solution; and
- e) after step (d), rinsing the solid support with an aqueous solution to provide a recycled solid support,

wherein said solid support is made of a non-woven fibrous matrix bonded to a porous support sheet or is a microcarrier.

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In claim 3, at line 1, the phrase --sodium hydroxide in said-- has been inserted before the phrase "sodium hydroxide solution".

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In claim 4, at line 1, the term "(d)" has been omitted and replaced with the term --(e)--.

In claim 5, at line 1, the term "(d)" has been omitted and replaced with the term --(e)--.

In claim 6, at line 1, the term "(d)" has been omitted and replaced with the term --(e)--.

In claim 7, at line 2, the term "(b)" has been omitted and replaced with the term --(c)--.

In claim 8, at line 2, the term "(d)" has been omitted and replaced with the term --(e)--.

In claim 9, at line 1, the term "(d)" has been omitted and replaced with the term --(e)--.

In claim 9, at line 2, the term "(d)" has been omitted and replaced with the term --(e)--.

In claim 10, at line 1, the term --said-- has been inserted before the term "non-woven".

In claim 10 at line 2, the term "a porous" has been omitted and replaced with the phrase --  
said porous--.

In claim 13, at line 1, before the term "comprises", insert the term --further--.

In claim 15, the term "comprises" has been omitted and replaced with the term --contains--.

In claim 16, after the term "wherein", insert the phrase --in step (a)--.

In claim 16, before the term "column", insert the term --external--.

Claim 17 has been amended to read as follows:

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17. The method of claim 1, further comprising after step (e):

f) sterilizing the cell culture system.

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Claim 18 has been amended to read as follows:

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18. The method of claim 14, further comprising after step (e):

f) sterilizing the external column.

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In claim 19, at line 1, the term "(d)" has been omitted and replaced with the term --(e)--.

In claim 19, at lines 3,4, and 5, each instance of the term " $l \cdot h^{-1} \cdot kg^{-1}$ " has been omitted and each replaced with the term  $--l \cdot h^{-1} kg^{-1}--$ .

In claim 20, at line 1, the term "(d)" has been omitted and replaced with the term --(e)--.

In claim 21, at line 1, the term "(d)" has been omitted and replaced with the term --(e)--.

In claim 22, at line 1, the term "(d)" has been omitted and replaced with the term --(e)--.

In claim 23, at line 1, the term "(c)" has been omitted and replaced with the term --(d)--.

In claim 23, at lines 3,4, and 5, each instance of the term " $l \cdot h^{-1} \cdot kg^{-1}$ " has been omitted and each replaced with the term  $--l \cdot h^{-1} kg^{-1}--$ .

In claim 24, at line 1, the term "(c)" has been omitted and replaced with the term --(d)--.

In claim 25, at line 1, the term "(c)" has been omitted and replaced with the term --(d)--.

In claim 26, at line 1, the term "(b)" has been omitted and replaced with the term --(c)--.

In claim 27, at line 1, the term "(b)" has been omitted and replaced with the term --(c)--.

In claim 28, at line 1, the term "(b)" has been omitted and replaced with the term --(c)--.

### REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

The state of the art at the time of the instant invention was made was such that various sterilizing and reuse methods in general for plastic tissue culture plates and vessels were known to the skilled artisan, as taught by Beltrán-Langarica, *et al* (*Methods in Cell Science*, 1983, 8(4), pages 173-176); Galin, *et al* (*J Am Intraocul Implant Soc*, 1983 Summer, 9(3), pages 290-292); and Sanborn, *et al* (*Applied and Environmental Microbiology*, Oct 1982, 44(4), pages 960-964), which teach and are distinguished from the instant method as follows:

Beltrán-Langarica *et al* teaches washing and sterilizing plastic tissue culture dishes for culturing of 3T3 cells (adhesive cells); however, does not teach non-woven fibrous matrix bonded to a porous support sheet or microcarrier (see entire document).

Galin *et al* teaches washing or sterilizing PMMA polymer intraocular lenses with triplicate aqueous NaOH washings; however, does not teach the instantly claimed materials (non-woven fibrous matrix bonded to a porous support sheet or microcarrier) or anchorage-dependent cell cultivation systems (see entire document, e.g. abstract).

Sanborn *et al* teaches plastic culture vessel microwave sterilization and reuse. Sanborn also teaches adherent cells; however does not teach non-woven fibrous matrix bonded to a porous support sheet or microcarrier (see entire document).



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Also, the claims are further distinguished in that one would not be motivated to recycle or reuse the instantly claimed non-woven fibrous matrix bonded to a porous support sheet or microcarrier material, especially in view of the prior art of NBSC (NBSC, "Fermentation & Cell Culture FAQs", IDS) which teaches to one of skill to not reuse the material (see entire document, e.g. page 7).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. KOSAR whose telephone number is (571)270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AARON J KOSAR/  
Examiner, Art Unit 1657

/Christopher R Tate/  
Primary Examiner, Art Unit 1655